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Solicitation of Public Review and Comment of Research Protocol: A Multicenter, Randomized Dose Response Study of the Safety, Clinical and Immune Response of Dryvax Administered to Children two to five Years of Age.  
{Docket No. 02N-0466}

My medical careers teacher has brought the smallpox issue to my attention, and we were asked to write letters supporting or opposing this issue. Now as an assistant in a nursery school, a person who looks forward to pursuing a career in the medical field, and a child lover, I have some very strong feelings on this issue.

My first concern is the well being of the child, which in this case doesn't seem as much of an issue to you. Children learn the most between the ages two to five, that's when they develop their fine and large motor skills. They develop these through they're daycares and nursery school settings, then more so at home because of the available resources to do so. They learn to interact with other children properly, they learn to share, color, draw, and express themselves as people. These things may seem like little kid games to you, but they form a very important base to the child's future. To remove these children from that setting for a whole month, for something no more then research is completely unethical, let alone the drama and terror this could bring to an innocent child's life. Children at that age don't understand that things are done for a reason all they understand is that there is a change in their daily routine, and it takes a while for children to adapt to change. By the time the children have gotten used to staying home everyday, they will be going back to their nursery schools and daycares, this will cause a whole lot of confusion for the child, and could have an impact on their social skills.

My second concern is the danger for the children, and also the people around them. In an article "Toddler testing of smallpox vaccine sought" it was stated "Based on the studies from the 1960's 15 out of every 1 million people vaccinated will suffer life-threatening reactions, and one or two of them will die." The concern for the children touching the injections site should be a huge factor. It's kind of like leaving a wet diaper on a child and telling them no it has to stay on. This would be very uncomfortable to the child, especially their parents telling them no don't touch, the more kids here no don't do something the more they want to do it, even adults it's just humankind. The temptation is always there. When you get the chicken pox as a kid you always scratch them, even when your told "it's going to leave a scar!" it doesn't matter to you at that point in time all you think about is it itches scratch it so what if it leaves a scar? But the dangers of the child itching this are far more worse then a scar. If even one child were to touch the injection site, then touch someone's eyes they could go blind!

My third concern is that testing 40 innocent healthy children with something they could in no way benefit from at this time, knowing there's a possibility of life threatening complication's is completely unethical. Let alone with the amount of children you are testing won't give you accurate results. In the article "Medical society supports 'Ring

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Vaccination' in case of smallpox outbreak" the AAP stated "Studies from the 1960's show approximately 1,200 people per 1 million immunized will suffer serious complications. Data from 1968 show at least 40 million immunized developed potentially life-threatening complications." The article had also mentioned the lack of knowledge that the general public has about the dangers of this vaccine. There is nothing to really go on here; there is no knowledge of what is going to happen, if the vaccine will even work!

In conclusion the risks are way too high to subject innocent children to something no more then a study that has no effect on the human population as of right now. If we were to receive anything leading us to the threat of a bioterrorist attack then I might think differently because we therefore wouldn't know what to do with the children, but as of right now there is no evidence of that, or any evidence that they even have the laboratory samples of smallpox. We are too unsure of this vaccine to go testing innocent children.